DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: July 15, 2005

From: Division of Chemical Research and Environmental Review

Subject: FAP 9M4682: National Fisheries Institute and Louisiana Department of Agriculture and Forestry, Ionizing Radiation for the Pasteurization of Fresh or Frozen Molluscan Shellfish.

To: DBGNR Division of Biotechnology and Gras Notification Review, HFS-255
Attn.: Lane Highbarger, Ph.D.

Introduction

The National Fisheries Institute (NFI) and Louisiana Department of Agriculture have submitted a petition to amend 21 CFR Part 179 - *Irradiation in the Production, Processing and Handling of Food*, to provide for the safe use of sources of ionizing radiation to irradiate refrigerated or frozen mollusks to reduce the microbial load on and prolong the shelf life of these foods.

This memorandum will address the potential for the formation of furan in molluscan shellfish as a result of their treatment with ionizing radiation.

During investigations relating to the Agency's review of a petition for the use of irradiation in certain foods (FAP 9M4697, see memorandum from the Division of Product Manufacture and Use to the Division of Product Policy, dated August 10, 2001), FDA scientists identified the substance furan resulting from the radiation treatment of apple juice (Dubois, P.; Zenz, H.; Stehlik, G.; Kaindl, K., "Analysis of the Volatile Compounds in Irradiated Apple and Grape Juices." Seibersdorf Project Report SPR-8, 1966). The presence of furan is a potential concern because, based on high-dose animal tests, furan is considered possibly carcinogenic to humans.

Because the original experiments were carried out prior to mass spectroscopic techniques and relied on chemical experiments which inferred the compound detected to be furan, the FDA, Division of Chemistry Research and Environmental Review performed some laboratory experiments using Gas Chromatography with mass spectral detection to determine if furan was generated as a result of the ionizing radiation. These experiments confirmed the presence of furan in irradiated apple juice; however, the amount of furan present was in the 5-10 ppb range (Morehouse and McNeal, unpublished results). Co-eluting with the furan was a larger peak which was identified as ethanol. It is possible that the large peak that is mentioned in the original report is a mixture of ethanol and furan. The FDA has developed a gas chromatography/mass spectrometry method to measure furan levels in food, which is posted on the FDA's website at http://www.cfsan.fda.gov/~lrd/pestadd.html#furan.

The Division of Chemistry Research and Environmental Review has investigated the possibility that furan may be formed in other foods during treatment with ionizing radiation. The Division investigated a variety of foods, including those for which prior approval for treatment with ionizing radiation has been granted, as well as foods for which the Agency has active petitions pending. Foods that have been investigated include clams and oysters.

Experimental Results

To investigate the possible formation of furan in molluscan shellfish, the Division purchased fresh shucked clams and oysters at a local grocery store. The shellfish was chopped using a food processor to produce a homogenous sample. A weighed amount of the homogenized product was placed in a 15 mL headspace vial, sealed using Teflon lined septum. The vials were then irradiated either frozen or on ice (-20 or 0-5 °C). The samples were irradiated at several different doses (form 0 to 10 kGy). The irradiated and control samples were then analyzed for furan using the GC/MS procedure using d4-furan as internal standard. The d4-furan was added in a known amount after the radiation treatment.

The results that were obtained demonstrated that furan was present in the oysters prior to the radiation treatment and due to the large variability of the presence of furan it was very difficult to see any increase in the amount of furan generated as a result of the ionizing radiation. If the oysters were prepared and irradiated the same day as purchased and then analyzed the next day (i.e., less than 36 hours between purchase and analysis), it was possible to see a small non-quantifiable increase in the amount of furan present in the oysters after radiation treatment. However, the amount of furan present in the oysters, even after treatment with a dose of 10 kGy, was still less than the level of furan that the FDA has determined to be the limit of quantitation (5ppb). If the oysters were then reanalyzed 48 hours later, the furan levels in irradiated and non-irradiated oysters were indistinguishable due to the much larger amount of endogenous furan formed.

Further experiments demonstrated that for oysters, the amount of furan present in the non-irradiated samples increased with storage at 0 to 5 °C. After 48 hours the amount of furan present in untreated oysters, and the variability of the amount of furan in the untreated oysters, was larger than, and masked any increase in the levels of furan that could be ascribed to the radiation treatment.

Our experiments for clams did not demonstrate this same effect of storage and did not demonstrate any increase in the levels of furan as a result of the ionizing radiation treatment.

Conclusions

From these experiments, the Division of Chemistry Research and Environmental Review concludes that the radiation treatment of molluscan shellfish will not result in an increase in the amount of furan over that which is present in the untreated shellfish.

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